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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,484	08/24/2001	Fabrice Duprat	1201-CIP-DIV-00	3868
35811	7590	04/20/2004	EXAMINER	
IP DEPARTMENT OF PIPER RUDNICK LLP ONE LIBERTY PLACE, SUITE 4900 1650 MARKET ST PHILADELPHIA, PA 19103			YAEN, CHRISTOPHER H	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,484

Applicant(s)

DUPRAT ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

RE: Duprat *et al*
Priority Date: 4 August 1998

1. The amendment filed 2/02/2004 is acknowledged and entered into the record. Accordingly, claims 1-8 and 16-23 are canceled without prejudice or disclaimer. Claims 9 and 11 are currently amended.
2. Claims 9-15 are therefore pending and examined on the merits.

Priority

3. The instant applicant claims priority to an earlier filed CIP application 08/749,816 which is now US Patent 6,013,470 (herein referred to as `470). However, `470 fails to provide the proper written description of a protein having SEQ ID No: 4 or any functionally equivalent derivative that is at least 85% identical. Therefore, the priority of the instant applicant is not afforded the earlier priority date of 11/15/1996. The earliest priority date used for prior art purposes will be 8/4/1998.

NEW ARGUMENTS

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 9-15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The disclosed utility for the isolated protein of SEQ ID No: 4 or functionally equivalent derivatives having at least 85% identity to SEQ ID No: 4 include the screening of agents or drugs that are capable of modulating the activity of potassium channels (page 3) and to use such agents or drugs as a means to treat or prevent diseases associated with the potassium channels (see page 3 and page 27). However, neither the specification nor any art of record teaches what the TASK protein is, how it functions, or a specific and well-established utility for any of the functionally equivalent derivatives claimed. Furthermore, the specification does not teach a relationship to any specific disease or establish any involvement in the etiology of any specific disease, so as to use any agent or drug which was screened with said TASK protein.

The specification as filed has not set forth either a specific or substantial utility for the claimed polypeptide of SEQ ID No: 4. The asserted utility of screening for agents or drugs for treating or preventing diseases associated with the polypeptide of SEQ ID No: 4 is not considered either specific or substantial. Such utilities can be applied broadly to any protein or polypeptide given a functional characteristic for which to screen. The specification nor the art of record has associated the polypeptide of SEQ ID No: 4 with any known disease nor has it been linked to the etiology of any specific disease. Further, the use of drugs or agents, which modulate the polypeptide of SEQ ID No: 4, has not set forth with any specific target for which to treat. The specification has essentially

essentially provided a starting point for which to look for disease or uses for the claimed polypeptide. Moreover, the specification has also failed to establish a substantial utility which can be applied with any "real world" utility because further experimentation is required to attribute a utility to the claimed polypeptide. The specification has not disclosed any specific disease or condition which would require the use of either the claimed polypeptide or agents which were screened using the claimed polypeptide of SEQ ID No: 4. "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing" and stated, in the context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." -- see *Brenner v. Manson*, 383 U.S. 519, 535-36, 148 USPQ 689, 696 (1996) and *Revised Interim Utility Guidelines Training Materials* (page 35).

The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed polypeptide and fragments thereof. Because the claimed invention is not supported by a specific asserted utility for the reasons set forth, credibility of any utility cannot be assessed.

Claims 9-15 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 9-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Leonaudakis *et al* (J. Neuroscience 1998 Feb;18(3):868-877). Leonoudakis *et al* teach a protein that is at least 85% identical to SEQ ID No: 4 (see attached homology search), wherein the protein comprises 2 P domains and four TMSs (see page 870 figure 1C). The limitations of claims 11-14 are considered inherent properties of a protein. Thus, the claimed protein appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

8. Claims 9-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Duprat *et al* (EMBO J 1997 September;16(17):5464-5471). Duprat *et al* teach the isolation of a human protein termed TASK which shares 90% identity to SEQ ID No: 4 (see attached homology search), wherein there are 2 P domains and 4 TMSs (see page 5465). It is also disclosed that the protein exhibits outward rectification at 2mM and no rectification

at 98mM (see abstract). It is also disclosed that the potassium channel cloned and isolated is a background channel (see page 5464) and that the channel operates at optimal activity when the pH range is between 6.7-7.7 (see abstract), wherein 90% activity is at pH 7.7 and 10% activity is at pH 6.7 (see abstract).

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed 2/2/2004.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
April 16, 2004


GARY NICKOL
PRIMARY EXAMINER